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10/561,413	11/24/2006	Kyung-Jin Yeum	108341-28	8051

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EXAMINER	
VAKILI, ZOHREH	
ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No.	Applicant(s)	
	10/561,413	YEUM, KYUNG-JIN	
	Examiner	Art Unit	
	ZOHREH VAKILI	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are presented for examination.

Applicant's Amendment filed August 2, 2010 has been received and entered into the present application. Claims 1-20 are pending and are herein examined on the merits.

Applicant's arguments, filed August 2, 2010 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-10, 13, and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Babish et al. (US Pub. No. 2002/0110604 A1).

Babish et al. teach a novel formulation that serves to synergistically inhibit the generation of free radicals and oxidative stress in animals. The formulation comprises a

carotenoid species (see abstract). The carotenoid species is a member selected from the group consisting of astaxanthin, beta-carotene, lutein, and lycopene (see paragraph 0024). The present invention further provides a method of dietary supplementation and **a method of treating oxidative stress or oxidative stress-based diseases** in warm-blooded animals which comprises providing to the animal suffering symptoms of oxidative stress the composition of the present invention (see paragraph 0030). A daily dose of the present dietary supplement would be formulated to deliver: 1 to 50 mg of a carotenoid species (see paragraph 0058). Other ingredients used in this composition are fats and oils (see paragraph 0062), which reads on claim 3, the limitation that the composition further comprises a lipophilic component. The dietary supplements composition is formulated into a capsule or tablet. The present composition may also be formulated in forms such as food, cereals or snack items (see paragraph 0063). The present invention contemplates treatment of all types of oxidative stress-based diseases (see paragraph 64). A composition having synergistic antioxidant activity comprising an effective of a carotenoid species selected from beta-carotene, lutein, and lycopene (see claim 6). The composition additionally containing one or more members of antioxidant and fats (see claim 10). Babish et al. further teach a method of normalization or therapeutic treatment of symptoms of oxidative stress in animals comprising administering to an animal a composition comprising effective amount of a carotenoid species and continuing said administration until said symptoms of oxidative stress are reduced (see claim 41).

As evidenced by Hoshino et al. (US Pat. No. 6869773 B2) aging is caused by oxidative damage (see col. 6, lines 52-53). It also provides a process for producing a carotenoid (see abstract).

Consequently, the reference anticipates the claimed invention defined in claims 1-3, 5-10, 13, and 15-18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babish et al. (US Pub. No. 2002/0110604 A1) and in view of Auweter et al. (US Pub No. 2002/0044991) (cited on IDS).

Babish et al. teach a novel formulation that serves to synergistically inhibit the generation of free radicals and oxidative stress in animals. The formulation comprises a carotenoid species (see abstract). The carotenoid species is a member selected from the group consisting of astaxanthin, beta-carotene, lutein, and lycopene (see paragraph

0024). The present invention further provides a method of dietary supplementation and **a method of treating oxidative stress or oxidative stress-based diseases** in warm-blooded animals which comprises providing to the animal suffering symptoms of oxidative stress the composition of the present invention (see paragraph 0030). A daily dose of the present dietary supplement would be formulated to deliver: 1 to 50 mg of a carotenoid species (see paragraph 0058). Other ingredients used in this composition are fats and oils (see paragraph 0062), which reads on claim 3, the limitation that the composition further comprises a lipophilic component. The dietary supplements composition is formulated into a capsule or tablet. The present composition may also be formulated in forms such as food, cereals or snack items (see paragraph 0063). The present invention contemplates treatment of all types of oxidative stress-based diseases (see paragraph 64). A composition having synergistic antioxidant activity comprising an effective of a carotenoid species selected from beta-carotene, lutein, and lycopene (see claim 6). The composition additionally containing one or more members of antioxidant and fats (see claim 10). Babish et al. further teach a method of normalization or therapeutic treatment of symptoms of oxidative stress in animals comprising administering to an animal a composition comprising effective amount of a carotenoid species and continuing said administration until said symptoms of oxidative stress are reduced (see claim 41).

Auweter et al. teach preparations of at least two active compounds suitable for the food sector and animal feed sector or for pharmaceutical and cosmetic applications having a multicore structure in which at least two cores of a multicore structure have a

different chemical composition, a process for their production and the use of these solid preparations to produce food supplements, and as additive to foods, animal feeds, pharmaceutical and cosmetic preparations (see abstract). The invention relates to solid preparations of at least two active compounds suitable for the food sector and animal feed sector or for pharmaceutical and cosmetic applications having a multicore structure, in particular carotenoid containing dry powders, a process for their production and the use of these solid preparations for producing food supplements and as additive to foods, animal feeds, pharmaceutical and cosmetic preparations [0001]. The objective is achieved according to the invention by solid preparations of at least two active compounds suitable for the food sector and animal feed sector or for pharmaceutical and cosmetic applications in the form of a multicore structure in which at least two cores of a multicore structure have a different chemical composition [0011]. Carotenoids, not only carotenes but also xanthophylls, for example **beta-carotene, lycopene, lutein**, astaxanthin, zeaxanthin, and capsanthin [0022]. Preferred embodiments of the inventive solid preparations are carotenoid-containing dry powders in the form of the multicore structure which comprise at least two of the mentioned carotenoids, selected from the group consisting of carotenes and xanthophylls [0023] Particular preference is given to those dry powders in which at least two cores (primary particles) comprise one carotenoid or more than one different carotenoids. In particular in the preparations at least two cores comprise only one representative of the carotenoid class of substances [0024]. Very particular preference is given to dry powders comprising a mixture of beta-carotene, lycopene and lutein [0028]. A dry

powder of this type comprises a multicore structure of secondary particles in which at least three primary particles have a different carotenoid composition, in each case one particle species comprising only beta-carotene, the second lycopene and the third only lutein [0029]. The content of .beta.-carotene, lycopene and lutein in the inventive dry powders is generally from 0.1 to 50% by weight, preferably from 1 to 35% by weight, particularly preferably from 5 to 25% by weight, very particularly preferably from 8 to 20% by weight, based on the total amount of the formulation [0030]. The quantitative ratio of the carotenoids present in the dry powder is 1 part of beta-carotene, from 0.02 to 20 parts of lycopene and from 0.02 to 20 parts of lutein, preferably 1 part of beta-carotene, from 0.1 to 5 parts of lycopene and from 0.1 to 5 parts of lutein, particularly preferably 1 part of beta-carotene, from 0.2 to 2 parts of lycopene and from 0.1 to 2 parts of lutein, very particularly preferably 1 part of beta-carotene, from 0.3 to 1.2 parts of lycopene and from 0.1 to 0.8 parts of lutein. [0031]. Food supplement preparations and pharmaceutical preparations which comprise the inventive dry powders are, inter alia, tablets, sugar-coated tablets and hard and soft gelatin capsules. Preferred food supplement preparations are tablets into which the dry powders are coincorporated, and soft gelatin capsules in which the carotenoid-containing multicore structures are present as oily suspension in the capsules. The carotenoid content in these capsules is from 0.5 to 20 mg of .beta.-carotene, from 0.5 to 20 mg of lycopene and 0.5 to 20 mg of lutein, preferably from 1 to 15 mg of beta-carotene, from 1 to 15 mg of lycopene and from 1 to 10 mg of lutein, particularly preferably from 2 to 10 mg of beta-carotene, from 2 to 10 mg of lycopene and from 1 to 5 mg of lutein [0055].

One of ordinary skill in the art would combine the teachings of above references since both references are directed toward a compostion and method comprising carotenoid.

It would have been obvious to a person skilled in the art to employ the teachings of the above mentioned references considering that such references teach all the components of the claimed invention in a pharmaceutical formulation.

One skilled in the art would have been motivated to employ the teachings of the mentioned above references since they relate to a composition comprising of carotenoid species in a nutritional and pharmaceutical formulation. The above references make clear that the claimed components have been previously used in a nutrient supplement composition and method of decreasing oxidative damage in a subject. As combined, the references would have resulted in the claimed invention.

Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, prima facie obvious over the cited arts.

Response to Arguments

Applicant argues Babish teaches that astaxanthin, beta-carotene, lutein, lycopene, zeaxanthn, and cantaxanthin are carotenoid species. However, Babish preferred carotenoid species is astaxanthin. (See paragraph [0024] of Babish's specification). Moreover, Babish has no appreciation for the use of *about 0. 1 to 20 mg lutein* or synergistic effects of combining *lutein* with beta-carotene and/or lycopene. In

fact, none of the examples of Babish demonstrate the use of lutein in the formulation, let alone a synergistic combination of *about 0. 1 to 20 mg lutein* with another carotenoid.

Applicant's arguments are not persuasive; Babish et al. teach a novel formulation that serves to synergistically inhibit the generation of free radicals and oxidative stress in animals. The formulation comprises a carotenoid species (see abstract). The carotenoid species is a member selected from the group consisting of astaxanthin, beta-carotene, lutein, and lycopene (see paragraph 0024). A daily dose of the present dietary supplement would be formulated to deliver: **1 to 50 mg** of a carotenoid species (see paragraph 0058). A composition having **synergistic antioxidant activity** comprising an effective amount of a carotenoid species selected from **beta-carotene, lutein, and lycopene** (see claim 6). The composition additionally containing one or more members of antioxidant and fats (see claim 10).

Applicant further argues since Babish does not teach or suggest the use of a synergistic combination of lutein with beta-carotene and/or lycopene, one of ordinary skill in the art would have no reason to look to Auweter. The only reason provided by the Office Action is that the references teach all the components of the claimed invention. It appears that the Office Action is simply picking and choosing features from various pieces of art and combining them in an attempt to arrive at the claimed invention.

Applicant's arguments are not persuasive; Auweter teaches the carotenoid content in these capsules is from 0.5 to 20 mg of .beta.-carotene, from 0.5 to 20 mg of

lycopene and 0.5 to 20 mg of lutein, preferably from 1 to 15 mg of beta-carotene, from 1 to 15 mg of lycopene and from 1 to 10 mg of lutein, particularly preferably from 2 to 10 mg of beta-carotene, from 2 to 10 mg of lycopene and from 1 to 5 mg of lutein [0055]. Same components with same dosage range in a formulation will necessarily deliver the synergistic effect. As discussed above Babish teaches a composition having **synergistic antioxidant activity** comprising an effective amount of a carotenoid species selected from **beta-carotene, lutein, and lycopene** (see claim 6). The composition additionally containing one or more members of antioxidant and fats (see claim 10). the Office Action does need to pick and choose features from various pieces of art and combining them in an attempt to arrive at the claimed invention. Both prior art references combined and individually teach a composition having **synergistic antioxidant activity** comprising an effective amount of a carotenoid species selected from **beta-carotene, lutein, and lycopene**. Further, the components and the dosage range that delivers a synergistic effect is taught by the prior art references.

Applicant's amendments and remarks have been carefully considered in their entirety, but fail to be persuasive in establishing error in the propriety of the present rejection.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner
1614

October 4, 2010

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614